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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	11/563,676	NAGHAVI ET AL.
	Examiner RENE TOWA	Art Unit 3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 55-58 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-54, 59 and 60 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 November 2006 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>11/10/08</u>	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-54 & 59-60, drawn to a thermal measurement apparatus, computer program and method for assessment of vascular reactivity in an individual, classified in class 600, subclass 474.
 - II. Claims 55-58, drawn to a treatment for improving vascular function and a method for determining the influence or efficacy thereof, classified in class 600, subclass 504.
2. The inventions are distinct, each from the other because of the following reasons:
Inventions I and II are directed to related apparatus and method. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants. For example, invention I merely requires a thermal energy measurement apparatus for assessment of vascular reactivity in an individual by measuring the individual's temperature before, and after application of a vasostimulant to determine the individual's response to the vasostimulant; whereas invention II pertains to a

treatment for improving vascular function and a method for determining the efficacy or influence thereof in an individual by determining whether there is improvement in the vascular function of the individual via monitoring of thermal values of said individual. As such, inventions I and II can have a materially different design, mode of operation, function, or effect in that invention I pertains to a diagnosing method that does not require any kind treatment as in invention II; whereas invention II pertains to an efficacy study, which does not require any vasostimulation as in invention I.

3. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. During a telephone conversation with Marilyn Huston on November 19, 2009 a provisional election was made without traverse to prosecute the invention of group I,

claims 1-54 & 59-60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 55-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on November 10, 2008 is being considered by the examiner.

Claim Objections

7. Claims 1-31 are objected to because of the following informalities:

In regards to claim 1, at line 7, the limitation "stimulant," twice, should apparently --vasostimulant-- as per line 6.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7-9, 12, 31 & 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 7-9 & 12, at line 2, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 31 & 40, at lines 4 & 2-3, respectively, the limitations "TF, TR, NP, SF, and SR" render the claim indefinite; for example, it is unclear what is meant by TF, TR, NP, SF and SR.

Similarly, in regards to claim 40, at line 3, the limitations "the area under the curve" render the claim indefinite; for instance, it is unclear to which "curve" the applicant's claim refers; for example, claim 32 from which the claim depends, only mentions "a plot," which may or may not be a curve.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. **Claims 1-4, 13, 20, 26 & 28, 32-34, 36, 41-43, 46 & 49** are rejected under 35 U.S.C. 102(a) as being anticipated by Bowman et al. (US 2003/0191395).

In regards to **claim 1**, Bowman et al. disclose(s) a thermal energy measurement apparatus, comprising:

a thermal energy sensor 10 adapted to measure temperature of a body part while not substantially changing the temperature of the body part, and

a recorder 22 coupled to the thermal energy sensor 10, wherein the thermal energy sensor 10 measures the temperature of the body part before and subsequent to the provision of a vasostimulant, and the recorder 22 reports the temperature of the body part prior to the provision of the stimulant and the temperature of the body part after provision of the stimulant (see fig. 1; see par 0014-0016, 0038 & 0040).

In regards to **claim 2**, Bowman et al. disclose(s) a thermal energy measurement apparatus, where the vasostimulant is physical such as an occlusive means for providing a reactive hyperemia stimulant by interrupting the blood flow to the body part for a period of time followed by ceasing the interruption of blood flow (see par 0015).

In regards to **claim 3**, Bowman et al. disclose(s) a thermal energy measurement apparatus, where the vasostimulant is chemical such as a local or systemic administration of the stimulant for inducing vascular dilation or constriction (see par 0016 & 0046).

In regards to **claim 4**, Bowman et al. disclose(s) a thermal energy measurement apparatus, wherein the vasostimulant is a vascular or neurovascular stimulant (see par 0016 & 0046).

In regards to **claim 13**, Bowman et al. disclose(s) a thermal energy measurement apparatus, wherein the thermal energy sensor 10 comprises a plurality of thermal energy sensors (12, 14, 16, 18) (see par 0036 & 0038).

In regards to **claim 20**, Bowman et al. disclose(s) a thermal energy measurement apparatus, further comprising a unit for measuring tissue heat capacity (see par 0037).

In regards to **claim 26**, Bowman et al. disclose(s) a thermal energy measurement apparatus, wherein the thermal energy sensor 10 is operable to measure thermal energy over a time period (see par 0040).

In regards to **claim 28**, Bowman et al. disclose(s) a thermal energy measurement apparatus, is used to evaluate neurovascular reactivity of the subject and thereby to evaluate vascular and neurovascular health (see abstract).

In regards to **claim 32**, Bowman et al. disclose(s) a method for assessment of vascular reactivity in an individual comprising:

locating a thermal energy sensor 10 on a target site on the individual (see fig. 1), wherein the thermal energy sensor 10 via thermistor 12 does not alter microcapillary flow (see par 0055), and

establishing a stable baseline temperature with the thermal energy sensor 10 at the site via temperature sensors 14, 16 and 18 (see par 0036);

providing a vasostimulant (i.e. a challenge such as a constriction or chemical challenge) to the individual (see par 0014-0016);

determining a temperature response to the vasostimulant (see par 0037-0038 & 0040); and

establishing a vascular reactivity assessment for the individual based on the temperature response (see par 0037-0038).

In regards to **claim 33**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, wherein the vasostimulant comprises occluding a blood supply to the

target site for a predetermined period of time and ceasing occlusion thereafter (see par 0015).

In regards to **claim 34**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, wherein the target site is an extremity (i.e. forearm) (see par 0036 & 0043).

In regards to **claim 36**, Bowman et al. disclose(s) a method for assessment of vascular reactivity further comprising monitoring a temperature response on a site remote from the target site via temperature sensors (14, 16, 18) (see par 0038).

In regards to **claim 41**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, wherein the health condition is endothelial function (see abstract).

In regards to **claim 42**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, wherein the health condition is neurovasculopathy (see par 0010).

In regards to **claim 43**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, further comprising assessing a endothelial function (see abstract).

In regards to **claim 46**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, further comprising measuring and recording a tissue heat capacity of the subject (see par 0037).

In regards to **claim 49**, Bowman et al. disclose(s) a method for assessment of vascular reactivity, further comprising measuring a blood flow velocity through an artery of the subject which supplies blood to the body part before, during, and after the provision of the vasostimulant (see par 0017).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 5, 14, 25, 27, 29, 37 & 54** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Nilsson et al. (US 4,379,461).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a plotting engine; wherein the thermal energy sensor comprises a probe operable to measure thermal energy of the surface of the body part without contacting the body part; wherein a second thermal energy sensor adapted for measurement of temperature of a corresponding contralateral body part while not substantially changing the temperature of the body part; wherein the thermal energy sensor is an infrared sensor.

However, **Nilsson et al.** disclose(s) a thermal energy measurement apparatus, comprising a plotting engine 10 that plots a temperature curve at least between the temperature of the body part prior to the provision of the vasostimulant and the temperature of the body part after provision of the vasostimulant (see fig. 2; col. 2, lines 64-68; col. 3, lines 1-8; col. 4, lines 61-68; col. 5, lines 1-7); wherein the thermal energy sensor comprises a probe 4 operable to measure thermal energy of the surface of the body part without contacting the body part (see fig. 1; col. 2, lines 9-24); wherein the apparatus includes a second thermal energy sensor adapted for measurement of temperature of a corresponding contralateral body part while not substantially changing

the temperature of the body part (see col. 5, lines 29-36); wherein the thermal sensor includes an infrared sensor (see col. 2, lines 9-24); wherein the method further includes additional health techniques such as plethysmography (see col. 5, lines 8-28).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a plotting engine and a second thermal energy sensor as taught by Nillson et al. in order to facilitate comparison of the measured parameters.

14. **Claims 6, 31, 38, 40 & 59-60** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Kopjas (US 3,463,854).

Bowman et al. disclose a method, as described above, that fails to explicitly teach the fall temperature (TF) change.

However, **Kopjas** teaches that it is known to determine the time required for the temperature of the body part to stabilize subsequent to the provision of the vasostimulant; wherein the method includes calculating one or more vascular responsiveness determinants such as the fall temperature (TF) change of the temperature response to the vasostimulant (see col. 3, lines 10-15 & 36-41).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a fall temperature (TF) change as taught by Kopjas in order to determine the temperature elevation of the body segment.

15. **Claim 39** is rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Barnea (US 6,117,075).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a plot of temperature versus time.

However, **Barnea** teaches that it is known to provide a plot of temperature versus time (see figs. 2 & 5).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a plot of temperature versus time as taught by Barnea in order to facilitate comparison of the measured parameters.

16. **Claims 7-8 & 30** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Zheng et al. (US 6,447,460).

Bowman et al. disclose a method, as described above, that fails to explicitly teach an ultrasound Doppler or a pulse wave velocity parameter.

However, **Zheng et al.** disclose(s) a thermal energy measurement apparatus, wherein the device further comprises a unit for measuring a hemodynamic parameter such as blood flow velocity using ultrasound Doppler; wherein the device further comprises a unit for measuring a vascular physiologic parameter such as pulse wave velocity (see abstract; see figs. 2 & 5).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with an ultrasound Doppler as taught by Zheng et al. in order to screen for deep vein Thrombosis.

17. **Claims 9-10 & 44** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Britton (US 5,853,372).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a photoplethysmograph.

However, **Britton** disclose(s) a thermal energy measurement apparatus, wherein the device further comprises a unit for measuring and recording hemodynamic parameters using near infrared light such as photoplethysmography (see abstract).

In regards to claim 9, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a photoplethysmograph as taught by Britton in order to detect the rate of change of blood flow through arteries of the user.

In regards to claim 10, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a laser Doppler flowmetry as claimed in order to detect the rate of change of blood flow through arteries of the user.

In regards to claim 44, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with an optical spectroscopy as claimed in order to detect the rate of change of blood flow through arteries of the user.

18. **Claims 11-12, 21-22, 35 & 47** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Leiden et al. (US 2003/0212316).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a unit for measuring blood pressure, heart rate, or an alerting device.

However, **Leiden et al.** teach that it is known to provide a thermal energy measurement apparatus, wherein the device further comprises a unit for measuring blood pressure (see abstract); wherein the computer system is coupled to an alerting device (see par 0032).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a blood pressure measuring unit and an alerting unit as taught by Leiden et al. in order to measure blood pressure and alert a healthcare professional.

19. **Claims 15, 24, 45** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Rubinstein (US 6,547,745).

Bowman et al. disclose a method, as described above, that fails to explicitly teach one or more units for measuring room temperature measurement, core temperature measurement; wherein the thermal energy sensor is adapted to be coupled to a surface of the body part by an attachment selected from a group consisting of a: mesh sleeve, ring, non-insulating material, mesh, disposable adhesive, watch, bracelet, or an article of clothing such as a glove.

However, **Rubinstein** teaches that it is known to provide a thermal energy measurement apparatus comprising one or more units for measuring room temperature measurement, core temperature measurement; wherein the thermal energy sensor is

adapted to be coupled to a surface of the body part by an attachment comprising a bracelet (see figs. 1 & 5).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with room temperature and core temperature sensor coupled to a bracelet as taught by Rubinstein in order to continually measure body temperature.

20. **Claims 16-18** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Mault (US 2002/0077766).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a thermal energy measurement apparatus, comprising a computer system that is coupled to the thermal energy sensor by a wireless connection; wherein the wireless connection comprises Bluetooth technology; wherein the computer system is a PDA.

However, **Mault** teaches that it is known to provide a thermal energy measurement apparatus (see par 0005), comprising a computer system that is coupled to the thermal energy sensor by a wireless connection (see fig. 1; see par 0006); wherein the wireless connection comprises Bluetooth technology (see par 0025); wherein the computer system is a PDA (see par 0004, 0025 & 0027).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a wireless connection and a PDA as taught by Mault in order to connect the physiological parameter to the public network where it can be available to healthcare professionals.

21. **Claims 19, 23, 48 & 52** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Schnall et al. (US 6,939,304).

Bowman et al. disclose a method, as described above, that fails to explicitly teach a pulse oximeter, an oxygen saturation or BMI.

However, **Schnall et al.** disclose an apparatus comprising a BMI (see col. 4, lines 27-31), an oxygen saturation measurement and a pulse oximeter (see col. 8, lines 33-40).

In regards to claim 19, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a tissue metabolic rate as claimed in order to determine oxygen saturation in the blood.

In regards to claims 23 & 48, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a pulse oximeter as taught by Schnall et al. in order to determine oxygen saturation in the blood.

In regards to claim 52, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with a BMI measurement as taught by Schnall et al. in order to correctly evaluate endothelial activity.

22. **Claims 50** are rejected under 35 U.S.C. 103(a) as obvious over Bowman et al. (US 2003/0191395) in view of Amano et al. (US 5,755,229).

Bowman et al. disclose a method, as described above, that fails to explicitly teach an artery stiffness measurement.

However, **Amano et al.** teach an artery stiffness measurement (see fig. 22).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the method of Bowman et al. with an artery stiffness measurement as taught by Amano et al. in order to determine the viscoelasticity of the subject's peripheral circulation tissue.

Allowable Subject Matter

23. **Claim 51, 53** is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RENE TOWA whose telephone number is (571)272-8758. The examiner can normally be reached on M-F, 2:00PM-10:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rene Towa/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736